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21

Application Number	10/791, 075
Filing Date	March 1, 2004
First Named Inventor	David W. Wiethug
Art Unit	3761
Examiner Name	Leslie R. Deale
Attorney Docket Number	212/560

ENCLOSURES (Check all that apply)

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name			
Signature	<i>Jay A. Lenker</i>		
Printed name	<i>JAY A. LENKER</i>		
Date	28 November 2007	Reg. No.	

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Signature	<i>Jay A. Lenker</i>		
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	Date	28 Nov 2007	

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To Whom It May Concern:

Dr. Jay Lenker has asked me to comment on an invention he and others submitted to the Patent and Trademark Office for review and approval and to further comment on the decision of the Patent and Trademark Office after their review to initially reject said invention on the principal grounds that a similar device (i.e. Stringer et al) is equivalent to that proposed by Lenker et al. As a surgeon who has performed thousands of cardiopulmonary bypass procedures over the last 35 years in a variety of research animal species with a plethora of available cardiopulmonary bypass components, I feel qualified to offer the following comments with regard these two inventions.

First, a well-known problem continues to exist today, with use of all available passive blood filters on the market. All filters utilized today which create circular flow in the filter by a tangential blood inlet, fail to remove smaller gaseous bubbles that pass into the bloodstream and into the cerebral circulation where they embolize neural tissues causing variable but significant neurologic dysfunction.

The Stringer et al. invention appears to be simply an amalgamation into a single unit of the standard individual components of a typical cardiopulmonary bypass circuit (i.e. blood pump, venous reservoir, oxygenator, heat exchanger and arterial filter). After reading this patent thoroughly, there appears to be nothing innovative regarding the individual elements in the Stringer invention with that of the individual components available through a number of manufacturers other than those inventors placed them into a single component. The Stringer invention does appear to accomplish two objectives. First, it would reduce the priming volumes of the currently available systems since most of the individual components require coupling together by tubing to make them a fully functional and integral system and these tubing sets add significantly to priming volumes. Second, with less priming volume and an integrated system, the Stringer invention would appear to reduce the time of priming and degassing of the circuit prior to its use on the patient.

The Stringer invention does not appear to remove bubbles (especially those of smaller diameter) more efficiently than current arterial filters (bubble traps). In fact, given the design of their integrated system, an argument could be made that their system is a less efficient bubble trap since the blood appears to be buffered somewhat from the other components (i.e. oxygenator venous reservoir) of the integrated system prior to it's entry into the arterial filter. This seems especially true for the Stringer invention where an axial flow centrifugal pump is used rather than a more standard conventional roller pump system. It is typical for the standard passive arterial filters that would include the Stringer integrated filter to be inefficient in removal of small diameter bubbles as these small gaseous elements are diluted within the pumped blood and cannot be extracted over the short transit times seen in the arterial filter. The Lenker invention, however, appears to impart substantial centrifugal forces on the blood as it passes through their filter that are much greater than that of presently available devices and the Stringer invention. The Lenker invention also includes a novel arrangement of the impeller, blood inlet, blood outlet, and gas collection region that permits gas forced to the center by the impeller to be removed from the blood before it is pumped back to the patient. Although the blood transit time across the Lenker device would not be any greater than the conventional systems, the additional energy imparted on the blood should forcefully remove all gaseous material much more efficiently. If I can be of any further assistance please feel free to contact me at 1-530-795-2356.

Sincerely

A handwritten signature in black ink that appears to read "E.M. Breznock".

E.M. Breznock, DVM, PhD

Director of Research Programs

BioSurgeon, Inc.



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November 27, 2007

Leslie R. Deak
Patent Examiner
Art Unit 3761

Dear Ms. Deak

I am writing in regard to patent application number 10/791,075 entitled 'Method and Apparatus for Removal of Gas Bubbles from Blood' – inventor David Wieting et al.

By way of introduction, I am a licensed physician in California and spent 10 years first assisting in cardiac surgery in Sacramento. In addition, I have been a successful inventor and developer of rotary blood pumps for use as ventricular assist devices and have numerous patents in this field. Consequently, I have strong opinions regarding Mr. Wieting's patent application.

I am very familiar with Mr. Wieting's patent application and, in fact, encouraged him to pursue his invention when he told me about it 5 years ago. I believe it is an important invention because there has not been a satisfactory solution to removing microscopic air bubbles from the blood during cardiopulmonary bypass. This issue has become of increasing importance as studies have emerged which show that post open heart patients suffer from impairment of higher intellectual function and neurocognitive deficits. It is thought that microembolic air bubbles may be responsible for these problems.

The invention proposed by Mr. Wieting would be a significant improvement over the prior art and is based on sound principles of fluid dynamics. Wieting's device would produce a high velocity vortex flow field in which less dense particles would collect in the center of the vortex. Since air is much less dense than plasma this effect would be very large and would be amplified by the high velocity vortex flow field possible with his device and not possible in the air removal part of the Stringer device.

I do not believe that the Stringer invention would accomplish the separation of micro air bubbles that could be achieved with the Wieting invention and they seem to me to be patentably distinct.

Sincerely



Richard Wampler, M.D.